Dear X,

Approximately 550,000 babies are born prematurely in the U.S. each year and according to the National Heart Lung and Blood Institute 10 percent of preterm babies develop neonatal respiratory distress syndrome (RDS). RDS is a potentially life-threatening lung condition and a critical complication for many babies in the NICU. Today Cornerstone Therapeutics announced a new study on treatments for RDS published in this month's *Journal of Perinatology*. The retrospective study is the first published evidence comparing all-cause, in-hospital mortality among the three animal derived surfactants used to treat neonatal RDS in the United States. The study demonstrates that the use of Curosurf® (poractant alfa) Intratracheal Suspension results in lower mortality rates compared to other animal derived surfactants.

I have included the press release below for your reference and would be happy to coordinate a time for you to speak with the lead author of the study, Rangasamy Ramanathan, M.D., F.A.A.P., Associate Division Chief of the Division of Neonatal Medicine at LAC+USC Medical Center and Children's Hospital Los Angeles. Dr. Ramanathan can discuss why this study is critical and how these results will help physicians continue to understand how to stabilize and improve outcomes in preterm infants who are struggling with RDS.

Thank you in advance for your consideration and I look forward to hearing from you soon. You can reach me at 919-457-0743.

Best,

Andrea Moody
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Press Release

FOR IMMEDIATE RELEASE

New Research Indicates Treating Neonatal Respiratory Distress Syndrome with CUROSURF® Results in Lower Rate of Mortality Compared to Competitive Surfactants

First of Its Kind Retrospective Comparison in More than 14,000 Premature Infants Published in the *Journal of Perinatology*

CARY, N.C., September 12, 2011 – Cornerstone Therapeutics (NASDAQ: CRTX), a specialty pharmaceutical company focused on acquiring, developing and commercializing niche respiratory products, today announced findings from a study comparing all-cause, in-hospital mortality in more than 14,000 preterm infants with respiratory distress syndrome (RDS). The retrospective study evaluated Cornerstone's CUROSURF® (poractant alfa) compared to Infasurf® (calfactant) and Survanta® (beractant). Overall, CUROSURF treatment for RDS was associated with a significantly reduced likelihood of death compared to Infasurf, and a trend toward reduced mortality when compared with Survanta. The findings were published in the September 1, 2011 online issue of the *Journal of Perinatology.*

"Cornerstone is extremely pleased with the results of this study. This research, especially among the smallest infants, reinforces why CUROSURF is the market leader in the U.S. and worldwide, and why we continue to see successful hospital conversions to CUROSURF therapy." said Craig A. Collard, Cornerstone's President and Chief Executive Officer. "When paired with CUROSURF's existing, extensive clinical evidence, we believe these data will give neonatologists further confidence that CUROSURF is an appropriate choice to treat babies with RDS."

Cornerstone licensed CUROSURF U.S. rights from Chiesi Farmaceutici S.p.A. (Parma, Italy) as part of a broader transaction it completed with Chiesi in May 2009.

About Respiratory Distress Syndrome

Neonatal RDS is a complication of prematurity that makes breathing difficult for infants with underdeveloped lungs. The condition is caused by a lack of adequate endogenous surfactant - a protective substance that helps to reduce surface tension in the lungs. Without adequate surfactant, it is extremely difficult for infants to fully inflate their lungs and to avoid alveolar collapse. With approximately 550,000 premature births in the United States per year[1], the National Heart Lung and Blood Institute reports that 10 of every 100 premature babies develop neonatal RDS, with nearly all infants born before 28 weeks of pregnancy developing RDS[2].

To treat this condition, physicians will often administer an exogenous surfactant shortly after birth. This surfactant is meant to reduce surface tension, helping to improve oxygenation and lung function. Today, physicians have a choice of three different animal-derived surfactants in the United States: CUROSURF, Infasurf or Survanta. Each features a unique composition, volume requirements and surfactant dosage.

About the Study
The study was a retrospective, observational, cohort study comparing all-cause, in-hospital mortality in 14,173 preterm infants with RDS treated with one of three surfactants between 2005 and 2009. Data were collected from the research database maintained by the Charlotte, N.C.-based Premier healthcare alliance. The Premier Hospital Database is a large U.S. hospital-based database, containing information on approximately 5.5 million annual hospital discharges (approximately one-fifth of all acute care hospitalizations in the U.S.) with day-by-day service level detail.This study included discharge data from 236 hospitals across the United States. Key study findings are as follows:

- When compared to infants treated with CUROSURF, the likelihood of mortality was 49.6 percent greater for Infasurf patients (p=0.043), and 37.0 percent greater for Survanta patients (p=0.053).
- There were no differences in mortality observed between the Infasurf and Survanta groups (p=0.626).
- The unadjusted mortality rates were lowest for the infants treated with CUROSURF (3.61 percent), followed by Survanta (4.58 percent) and Infasurf (5.95 percent).

When stratified by birth weight, the greatest benefits were recognized by the smallest infants (500-749g), the population with the highest mortality in the study. In this group, the unadjusted mortality rate was significantly lower for CUROSURF treated infants (11.72 percent) versus those treated with Survanta (17.39 percent) or Infasurf (20.67 percent).

"The clinical implications of this research are important for many reasons," said Rangasamy Ramanathan, M.D., F.A.A.P., lead author and Associate Division Chief of the Division of Neonatal Medicine at LAC+USC Medical Center and Children's Hospital Los Angeles. "This is the first direct comparison between all three products and the largest, retrospective study with surfactants to date. This information is critical in neonatal intensive care units (NICUs) as we work to stabilize and improve outcomes in preterm infants who are struggling with RDS."

Limitations of this retrospective study include database restrictions, such as lack of information on the precise cause of death, number of surfactant doses and antenatal steroid use.

This study was sponsored by Chiesi Farmaceutici S.p.A.

Indication
CUROSURF® Intratracheal Suspension is indicated for the treatment (rescue) of Respiratory Distress Syndrome (RDS) in premature infants. CUROSURF® Intratracheal Suspension reduces mortality and pneumothoraces associated with RDS.

Important Safety Information
CUROSURF is intended for intratracheal use only. THE ADMINISTRATION OF EXOGENOUS SURFACTANTS, INCLUDING CUROSURF, CAN RAPIDLY AFFECT OXYGENATION AND LUNG COMPLIANCE. Therefore, infants receiving CUROSURF should receive frequent clinical and laboratory assessments so that oxygen and ventilatory support can be modified in response to respiratory changes.

CUROSURF should only be administered by those trained and experienced in the care, resuscitation, and stabilization of preterm infants.

TRANSIENT ADVERSE EFFECTS SEEN WITH THE ADMINISTRATION OF CUROSURF INCLUDE BRADYCARDIA, HYPOTENSION, ENDOTRACHAEL TUBE BLOCKAGE, AND OXYGEN DESATURATION. These events require stopping CUROSURF administration and taking appropriate measures to alleviate the condition. After the patient is stable, dosing may proceed with appropriate monitoring.

Please see full prescribing information at www.curosurf.com.

References

1. National Vital Statistics Reports (2009, March 18). Vol. 57, (12, p. 14)
2. National Heat Lung and Blood Institute (2009, September 01). *What is Respiratory Distress Syndrome?* Retrieved August 30, 2011, from http://www.nhlbi.nih.gov/health/health-topics/topics/rds

About Cornerstone Therapeutics

Cornerstone Therapeutics Inc. (Nasdaq: CRTX), headquartered in Cary, N.C., is a specialty pharmaceutical company focused on developing, acquiring, and commercializing products for the respiratory, hospital and related specialty markets. Key elements of the Company's strategy are to focus on identifying therapeutic niches within respiratory, hospital and related specialty markets to leverage existing business and create new opportunities; promote the Company's current products to high prescribing physicians through the Company's respiratory sales force and to hospital-based healthcare professionals through the Company's hospital sales force; license or acquire rights to existing patent- or trade secret-protected, branded products, which can be promoted through the same channels to generate on-going high-value earnings streams; advance the Company's development projects and further build a robust pipeline; and generate revenues by marketing approved generic products through the Company's wholly owned subsidiary, Aristos Pharmaceuticals, Inc.

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